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**CFSAN/Office of Food Additive Safety**

**July 2006**

# COLOR ADDITIVE STATUS LIST

*Formerly called Appendix A of the Investigations Operations Manual (IOM); New items are **highlighted in yellow**. If you are using an older web browser and you do not see the **highlighting**, you may download this document in [PDF \(77 KB\)](#) for printing.*

## [Food Additive Status List](#)

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## Preface

This status list provides current information concerning color additives, and will enable you to determine the status and limitations of most color additives likely to be encountered in a food, drug, device, or cosmetic establishment.

To maintain concise form, this list is limited in many respects involving certification, regulations, labeling, etc. For specific details concerning these matters, please refer to the source documents, Code of Federal Regulations (CFR, Title 21, Parts 70 to 82) and to the Federal Food, Drug, and Cosmetic Act, as amended, Sections 601(e), 602(e), 706, [21 U.S.C. 361(e), 362(e), 376] and as it pertains to Sections 201(s)(3) and (t), 402(c), 403(m), 501(a), and 502(m) [21 U.S.C 321(s)(3), and (t), 342(c), 343(m), 351(a), and 352(m)].

Any color additives not included in this listing and found in the possession of manufacturers or processors where they may be used in foods, drugs, devices, or cosmetics should be referred to your district for consideration. Your Servicing Laboratory for color analysis is also a good reference source.

LAKES: Color additive lakes are provisionally listed under 21 CFR 81.1. Part 82 of 21 CFR explains how lakes may be manufactured and named and lists the color additives that may be used to manufacture lakes. All lakes are subject to certification.

Examples of nomenclature of lakes:

- The name of a lake is formed from the name of the color additive combined with the name of the basic radical and the word "Lake". For example, the name of the lake prepared by extending the aluminum salt of FD&C Blue No. 1 upon alumina would be FD&C Blue No. 1 - Aluminum Lake.
- If a lake is prepared by extending an FD&C color additive on a substratum other than alumina, the symbol "FD&C" will be replaced by "D&C". For example, the name of the

lake prepared by extending the aluminum salt of FD&C Blue No. 1 upon a substratum other than alumina would be D&C Blue No. 1- Aluminum Lake.

NOTE: You are cautioned that this Exhibit is condensed and should be used for screening and guidance only. When you encounter situations involving possible violations of color additive regulations check the latest basic document as indicated in the second paragraph of this preface. Be certain of the complete status and report the facts. It is the district responsibility to instigate appropriate action, not yours. Do not advise firms to destroy stocks of possible suspect merchandise or institute recalls without district clearance.

### LIST 1

Color additives subject to certification and permanently listed (unless otherwise indicated) for use in **FOOD**. Most are also listed for use in **DRUGS AND COSMETICS** as noted. (None of these colors may be used in products that are for use in the area of the eye, unless otherwise indicated).

**FD&C Blue #1** - Food, drugs and cosmetics, including drugs and cosmetics for eye area - GMP - 74.101, 74.1101, 74.2101, 82.101

**FD&C Blue #1 Aluminum Lake** - Drugs and cosmetics for eye area - GMP - 74.1101, 74.2101, 82.101

**FD&C Blue #2** - Food and ingested drugs - GMP - 74.102, 74.1102; sutures - see medical devices - 74.3102.

**FD&C Blue #2 Aluminum Lake on alumina** - Bone cement - see medical devices - 74.3102, 82.102

**FD&C Green #3** - Food, drugs and cosmetics - GMP - 74.203, 74.1203, 74.2203, 82.203

**FD&C Red #3** - Food and ingested drugs - GMP - 74.303, 74.1303. May no longer be used in cosmetics, external drugs, and lakes

**FD&C Red #40 and its Aluminum Lake** - Food, drugs and cosmetics, including drugs and cosmetics for eye area - GMP. Other lakes for food, drugs and cosmetics are also permanently listed - 74.340, 74.1340, 74.2340

**FD&C Yellow #5** - Food, drugs and cosmetics, including drugs and cosmetics for eye area - GMP - 74.705, 74.1705, 74.2705, 82.705

**FD&C Yellow #5 Aluminum Lake** - Drugs and cosmetics for eye area - GMP - 74.1705, 74.2705, 82.705

**FD&C Yellow #6** - Food, drugs and cosmetics - GMP - 74.706, 74.1706, 74.2706, 82.706

**FD&C Lakes** (See Preface of this exhibit) - Provisionally listed. May be prepared from any of the above certified FD&C colors, except FD&C Red #3 - GMP - 81.1, 82.51

**Citrus Red #2** - Skins of mature oranges -  $\leq$  2 ppm by wt. of whole fruit - 74.302 Orange B - Surfaces and casings of frankfurters or sausages -  $\leq$  150 ppm by wt. of finished product - 74.250

**Use of the following color additives is no longer authorized or has been restricted:**

- FD&C Green #1 - Removed from list - 81.30(d)
- FD&C Green #2 - Removed from list - 81.30(d)
- FD&C Red #1 - Removed from list - 81.10(c), 81.30(b)(1)
- FD&C Red #2 - Removed from list - 81.10(f), Feb. 13, 1976 - 81.30(j)
- FD&C Red #3 - All lakes, all cosmetics, and external drugs removed from list - 81.10(u), Feb. 1, 1990 - 81.30(u). Use of FD&C Red #3, but not its lakes, in food and ingested drugs is allowed.
- FD&C Red #4 - Food, ingested drugs, and ingested cosmetics removed from list. Use in externally applied drugs and cosmetics is allowed - 81.10(d), Sep. 23, 1976 - 81.30(c).
- FD&C Violet #1 - Removed from list - 81.10(e), Apr. 10, 1973 - 81.30(h)

**LIST 2**

Color additives subject to certification and permanently listed (unless otherwise indicated) for **DRUG AND COSMETIC** use. (None of these colors may be used in products that are for use in the area of the eye unless otherwise indicated)

**D&C Black #2** - Only for the following cosmetics: eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel - GMP - 74.2052

**D&C Green #5** - For drugs and cosmetics including drugs and cosmetics for eye area - GMP - 74.1205, 74.2205, 82.1205

**D&C Orange #5** - Drugs: mouthwashes and dentifrices that are ingested drugs (GMP), and external drugs (at most 5 mg per day). Cosmetics: lipsticks (at most 5% by wt. of finished product), mouthwashes and dentifrices that are ingested cosmetics, and external cosmetics (GMP) 74.1255, 74.2255, 82.1255

**D&C Red #6** - For drugs (combined total of D&C Red No.6 & D&C Red No. 7 < 5 mg per day); For cosmetics (GMP) -74.1306, 74.2306, 82.1306

**D&C Red #7** - For drugs (combined total of D&C Red No.6 & D&C Red No. 7 < 5 mg per day); For cosmetics (GMP) -74.1307, 74.2307, 82.1307

**D&C Red #21** - For drugs generally and cosmetics - GMP -74.1321, 74.2321, 82.1321

**D&C Red #22** - For drugs generally and cosmetics - GMP -74.1322, 74.2322, 82.1322

**D&C Red #27** - For drugs generally and cosmetics - GMP -74.1327, 74.2327, 82.1327

**D&C Red #28** - For drugs generally and cosmetics - GMP -74.1328, 74.2328, 82.1328

**D&C Red #30** - For drugs generally and cosmetics - GMP -74.1330, 74.2330, 82.1330

**D&C Red #33** - Drugs: ingested drugs other than mouthwashes and dentifrices (at most 0.75 mg per day); and mouthwashes, dentifrices, and external drugs (GMP). Cosmetics: lipsticks (at most 3% by wt. of finished product); and mouthwashes, dentifrices and external cosmetics (GMP) 74.1333, 74.2333, 82.1333

**D&C Red #36** - Drugs: ingested drugs, other than mouthwashes and dentifrices, if taken continuously for < 1 year (at most 1.7 mg per day); ingested drugs if taken continuously for > 1 year (at most 1.0 mg per day); and external drugs (GMP). Cosmetics: lipsticks (at most 3% by wt. of finished product), and external cosmetics (GMP) 74.1336, 74.2336, 82.1336

**D&C Yellow #10** - For drugs generally and cosmetics -GMP -74.1710, 74.2710, 82.1710

**D&C Lakes (See Preface of this Exhibit)** - Provisionally listed. May be prepared from any of the FD&C or D&C color additives listed in part 82

**Use of the following color additives is no longer authorized or has been restricted:**

- D&C Black #1 - Sep. 4, 1966 - 81.30(d)
- D&C Blue #6 - Use in drugs and cosmetics is no longer authorized. 81.10(n); use in sutures is allowed (Dec. 13, 1977) - 81.30(o)
- D&C Blue #7 - Sep. 4, 1966 - 81.30(d)
- D&C Green #6 - Use in ingested drugs and ingested cosmetics is no longer authorized Mar. 27, 1981 - 81.10(o). Use in external drugs external cosmetics, and sutures is allowed
- D&C Green #7 - Sep. 4, 1966 - 81.30(d)
- D&C Orange #3 - Sep. 4, 1966 - 81.30(d)
- D&C Orange #8 - Sep. 4, 1966 - 81.30(d)
- D&C Orange #10 - Use in ingested drugs and ingested cosmetics is no longer authorized - 81.10(m), Apr. 28, 1981 - 81.30(n). Use in external drugs and external cosmetics is allowed
- D&C Orange #11 - Use in ingested drugs and ingested cosmetics is no longer authorized - 81.10(m), Apr. 28, 1981 - 81.30(n). Use in external drugs and external cosmetics is allowed
- D&C Orange #14 - Sep. 4, 1966 - 81.30(d)
- D&C Orange #15 - Sep. 4, 1966 - 81.30(d)
- D&C Orange #16 - Sep. 4, 1966 - 81.30(d)
- D&C Orange #17 - Removed from list Mar. 31, 1983 - 81.10(s)
- D&C Red #5 - Sep. 4, 1966 - 81.30(d)
- D&C Red #8 - Removed from list Jan. 6, 1987 - 81.10(t), 81.30(s)(1); July 15, 1988 - 81.30(s)(3)
- D&C Red #9 - Removed from list Jan. 6, 1987 - 81.10(t), 81.30(s)(1); July 15, 1988 - 81.30(s)(3)
- D&C Red #10 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)
- D&C Red #11 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)
- D&C Red #12 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)
- D&C Red #13 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)
- D&C Red #14 - Sep. 4, 1966 - 81.30(d)
- D&C Red #18 - Sep. 4, 1966 - 81.30(d)
- D&C Red #19 - Removed from list Feb. 4, 1983 - 81.10(q)(1)
- D&C Red #24 - Sep. 4, 1966 - 81.30(d)

- D&C Red #29 - Sep. 4, 1966 - 81.30(d)
- D&C Red #35 - Sep. 4, 1966 - 81.30(d)
- D&C Red #37 - Removed from list Feb 4, 1983 and June 6, 1986 - 81.10(q)
- D&C Red #38 - Sep. 4, 1966 - 81.30(d)

### **LIST 3**

Color Additives subject to certification and permanently listed (unless otherwise indicated) for use in **EXTERNALLY APPLIED DRUGS & COSMETICS**. (None of these colors may be used in products that are for use in the area of the eye)

**D&C Brown #1** Only external cosmetics - GMP - 74.2151

**FD&C Red #4** - For use only in externally applied drugs and cosmetics - GMP - 74.1304, 74.2304, 82.304

**D&C Red #17** - GMP - 74.1317, 74.2317, 82.1317

**D&C Red #31** - GMP - 74.1331, 74.2331, 82.1331

**D&C Red #34** - GMP - 74.1334, 74.2334, 82.1334

**D&C Red #39** - Only as an external drug in quaternary ammonium germicidal solutions (at most 0.1% by wt. of the finished product) 74.1339

**D&C Violet #2** - External drugs and cosmetics (GMP) and contact lenses, sutures, haptics and tacks (see medical devices) 74.1602, 74.2602, 82.1602

**Ext. D&C Violet #2** - For external cosmetics only - GMP - 74.2602a

**D&C Blue #4** - GMP - 74.1104, 74.2104, 82.1104

**D&C Green #6** - GMP - 74.1206, 74.2206, 82.1206

**D&C Green #8** - Limit  $\leq$  0.01% by wt of finished drug or cosmetic - 74.1208, 74.2208

**D&C Yellow #7** - GMP - 74.1707, 74.2707, 82.1707

**Ext. D&C Yellow #7** - GMP - 74.1707a, 74.2707a, 82.2707a

**D&C Yellow #8** - GMP - 74.1708, 74.2708, 82.1708

**D&C Yellow #11** - GMP - 74.1711, 74.2711

**D&C Orange #4** - GMP - 74.1254, 74.2254, 82.1254

**D&C Orange #10** - GMP - 74.1260, 74.2260, 82.1260

**D&C Orange #11** - GMP - 74.1261, 74.2261, 82.1261

**Ext. D&C Lakes (See Preface of this Exhibit)** - The only permitted Ext. D&C lake is Ext. D&C Yellow No. 7 lake prepared from Ext. D&C Yellow No. 7 (GMP) 81.1, 82.2051, 82.2707a

**Use of the following color additives is no longer authorized:**

- Ext. D&C Blue #1 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Red #11 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Blue #4 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Red #13 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Green #1 - Nov. 29, 1977 - 81.10(k)
- Ext. D&C Red #14 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Orange #1 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Red #15 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Orange #3 - Jul. 1, 1968 - 81.30(e)
- Ext. D&C Yellow #1 - Dec. 13, 1977 - 81.10(i)
- Ext. D&C Orange #4 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Red #1 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Yellow #3 - Jul. 1, 1968 - 81.30(e)
- Ext. D&C Red #2 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Yellow #5 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Red #3 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Yellow #6 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Red #8 - Jul. 1, 1968 - 81.30(e)
- Ext. D&C Yellow #9 - 81.10(a)
- Ext. D&C Red #10 - Sep. 4, 1966 - 81.30(d)
- Ext. D&C Yellow #10 - 81.10(a)

**LIST 4**

Color additives exempt from certification and permanently listed for **FOOD** use.

**Algae meal, dried** - Chicken feed only:  $\leq 0.3\%$  ethoxyquin in meal  $\leq 150$  ppm ethoxyquin in final feed - 73.275

**Annatto extract** - GMP - 73.30

**Astaxanthin** - Salmonid fish feed only:  $\leq 80$  mg per kg of finished feed - 73.35

**Beet juice (as vegetable juice)** - GMP - 73.260

**Beet powder (Dehydrated beets)** - GMP - 73.40

**Beta-Apo-8'-carotenal** - General use:  $\leq 15$  mg/lb of solid or semisolid food or per pint of liquid food - 73.90

**Beta carotene, natural and synthetic** - GMP - 73.95

**Canthaxanthin** - General use:  $\leq 30$  mg/lb of solid or semisolid food or per pint of liquid food; broiler chicken feed:  $\leq 4.41$  mg per kg (4 gm/ton) of complete feed; salmonid fish feed:  $\leq 80$  mg per kg (72 gm/ton) of finished feed - 73.75

**Caramel** - GMP - 73.85

**Carmine** - GMP - 73.100

**Carrot oil** - GMP - 73.300

**Cochineal extract** - GMP - 73.100

**Corn endosperm oil** - Chicken feed only - 73.315

**Cottonseed flour, toasted partially defatted cooked** - GMP - 73.140

**Ferrous gluconate** - Ripe olives only - GMP - 73.160

**Ferrous lactate** - Ripe olives only - GMP - 73.165

**Fruit juice** - GMP - 73.250

**Grape color extract** - Nonbeverage food only - 73.169

**Grape skin extract (enocianina)** - Still and carbonated drinks and ades, beverage bases and alcoholic beverages (in accordance with Parts 4 & 5 of 27 CFR) - 73.170

**Haematococcus algae meal** - Salmonid fish feed only. Total astaxanthin from all astaxanthin color additive sources listed in part 73,  $\leq 80$  mg per kg of finished feed - 73.185

**Synthetic iron oxide** - Sausage casings for humans:  $\leq 0.10\%$  by wt. of finished food; cat & dog food:  $\leq 0.25\%$  by wt of finished food - 73.200

**Lycopene, tomato extract or concentrate** - GMP - 73.585

**Paprika & Paprika oleoresin** - GMP - 73.340 & 73.345

**Phaffia yeast** - Salmonid fish feed only. Total astaxanthin from all astaxanthin color additive sources listed in part 73,  $\leq 80$  mg per kg of finished feed - 73.355

**Riboflavin** - GMP - 73.450

**Saffron** - GMP - 73.500

**Sodium copper chlorophyllin** - Citrus-based dry beverage mixes only:  $\leq 0.2$  percent by wt. of the dry mix - 73.125

**Tagetes (Aztec marigold) meal and extract** - Chicken feed only: ethoxyquin content  $\leq 0.3\%$  by wt. of additive and  $\leq 150$  ppm by wt. of final feed - 73.295

**Titanium dioxide** -  $\leq 1.0\%$  by wt. of food - 73.575

**Turmeric & Turmeric oleoresin** - GMP - 73.600 & 73.615

**Ultramarine blue** - Salt for animal feed only:  $\leq 0.5\%$  by wt. of salt - 73.50

**Vegetable juice** - GMP - 73.260

**Use of the following color additives is no longer authorized:**

- Alkanet (Alkane)
- Calcium carbonate - Allowed in drugs

- Carbon black
- Charcoal - NF XI
- Cudbear
- Ferric chloride
- Ferrous sulfate
- Logwood, chips & extract - Logwood extract is still permitted in sutures
- Safflower (American saffron)

### LIST 5

Color additives exempt from certification and permanently listed for **DRUG** use. (None of these color additives may be used in products that are for use in the area of the eye, unless otherwise indicated.).

**Alumina** - Drugs generally - GMP - 73.1010

**Aluminum powder** - Externally applied drugs, including those for eye area use - GMP - 73.1645

**Annatto extract** - Drugs generally, including those for eye area use - GMP - 73.1030

**Beta-carotene, natural and synthetic** - Drugs generally, including those for eye area - GMP - 73.1095

**Bismuth oxychloride** - Externally applied drugs only, including those for eye area - GMP - 73.1162

**Bronze powder** - Externally applied drugs only, including those for eye area - GMP - 73.1646

**Calcium carbonate** - Drugs generally - GMP - 73.1070

**Canthaxanthin** - GMP - Ingested drugs only - 73.1075

**Caramel** - Drugs generally - GMP - 73.1085

**Carmine** - Drugs generally - GMP - 73.1100

**Chlorophyllin, copper complex** - Dentifrices that are drugs -  $\leq 0.1\%$  by wt. - 73.1125

**Chromium hydroxide, green** - Externally applied drugs, including those for eye area - GMP - 73.1326

**Chromium oxides greens** - Externally applied drugs, including those for eye area - GMP - 73.1327

**Cochineal extract** - Drugs generally - GMP - 73.1100

**Copper, metallic powder** - Externally applied drugs, including those for eye area - GMP - 73.1647

**Potassium sodium copper chlorophyllin (Chlorophyllin copper complex)** - Dentifrices that are drugs -  $\leq 0.1\%$  by wt. - 73.1125

**Dihydroxyacetone** - Externally applied drugs intended to impart a color to the human body - GMP - 73.1150



**Ferric ammonium ferrocyanide (Iron Blue)** - Externally applied drugs, including those for eye area - GMP - 73.1298

**Ferric ferrocyanide (Iron Blue)** - Externally applied drugs, including those for eye area - GMP - 73.1299

**Guanine (Pearl essence)** - Externally applied drugs, including those for eye area - GMP - 73.1329

**Mica** - Dentifrices and externally applied drugs, including those for eye area - GMP - 73.1496

**Pyrophyllite** - Externally applied drugs - GMP - 73.1400

**Synthetic iron oxide** - Drugs generally. Limit for ingested drugs  $\leq$  5 mg elemental iron per day - 73.1200

**Talc** - Drugs generally - GMP - 73.1550

**Titanium dioxide** - Drugs generally, including those for eye area - GMP - 73.1575

**Zinc oxide** - Externally applied drugs, including those for eye area - GMP - 73.1991

**Use of the following color additives is no longer authorized:**

- Bone Black
- Charcoal NF XI
- Chlorophyll copper complex
- Fustic
- Ultramarine blue - use in cosmetics is allowed

### **LIST 6**

Color additives exempt from certification and permanently listed for **COSMETIC** use. (None of these colors may be used in products that are for use in the area of the eye, unless otherwise indicated)

**Aluminum powder** - Externally applied cosmetics, including those for eye area - GMP - 73.2645

**Annatto** - Cosmetics generally, including those for eye area - GMP - 73.2030

**Bismuth citrate** - For cosmetics intended to color hair on scalp only (Not for coloring eyelashes or eyebrows or other body hair) -  $\leq$  0.5% (wt/v) - 73.2110

**Bismuth oxychloride** - Cosmetics generally, including those for eye area - GMP - 73.2162

**Bronze powder** - Cosmetics generally, including those for eye area - GMP - 73.2646

**Caramel** - Cosmetics generally, including those for eye area - GMP - 73.2085

**Carmin** - Cosmetics generally, including those for eye area - GMP - 73.2087

**Beta-carotene** - Cosmetics generally, including those for eye area - GMP - 73.2095

**Chromium hydroxide green** - Externally applied cosmetics, including those for eye area -

GMP - 73.2326

**Chromium oxide greens** - Externally applied cosmetics, including those for eye area - GMP - 73.2327

**Copper, metallic powder** - Cosmetics generally, including those for eye area - GMP - 73.2647

**Dihydroxyacetone** - Externally applied cosmetics - GMP - 73.2150

**Disodium EDTA-copper** - Cosmetic shampoos - GMP - 73.2120

**Ferric ammonium ferrocyanide** - Externally applied cosmetics, including those for eye area - GMP - 73.2298

**Ferric ferrocyanide** - Externally applied cosmetics, including those for eye area - GMP - 73.2299

**Guaiazulene (Azulene)** - Externally applied cosmetics - GMP - 73.2180

**Guanine (Pearl essence)** - Cosmetics generally, including those for eye area - GMP - 73.2329

**Henna** - For coloring hair only, not for coloring eyelashes or eyebrows - 73.2190

**Iron oxides** - Cosmetics generally, including those for eye area - GMP - 73.2250

**Lead acetate** - For coloring hair only, not for coloring mustaches, eyelashes, eyebrows or other body hair. Limit  $\leq 0.6\%$  (wt/v) - 73.2396

**Luminescent zinc sulfide** - Externally applied cosmetics (nail polish and facial) - 73.2995

**Manganese Violet** - Cosmetics generally, including those for eye area - GMP - 73.2775

**Mica** - Cosmetics generally, including those for eye area - GMP - 73.2496

**Potassium sodium copper chlorophyllin (Chlorophyllin copper complex)** - Cosmetic dentifrices -  $\leq 0.1\%$  by wt. May be used only in combination with the substances listed in 21 CFR 73.2125(b)(2) - 73.2125

**Pyrophyllite** - Externally applied cosmetics - GMP - 73.2400

**Silver** - Fingernail polish -  $\leq 1\%$  by wt. - 73.2500

**Titanium dioxide** - Cosmetics generally, including those for eye area - GMP - 73.2575

**Ultramarines (Blue, Green, Pink, Red & Violet)** - Externally applied cosmetics, including those for eye area - GMP - 73.2725

**Zinc oxide** - Cosmetics generally, including those for eye area - GMP - 73.2991

**Use of the following color additives is no longer authorized:**

- Alloxan
- Bone black
- Carbon black (channel process)
- Carminic acid
- Chlorophyll copper complex
- Cobaltous aluminate (Cobalt Blue)

- Cochineal
- Fuller's earth
- Gloss white
- Graphite
- Kieselguhr (Diatomite)
- Lithopone
- Logwood (Gluewood, Campeche wood)
- 4-Methyl-7-diethylaminocoumarin (MDAC)
- B-Methyl umbelliferone
- Potassium ferrocyanide
- Sienna
- Umber
- Vermiculite
- Zirconium oxide
- Zirconium silicate

### LIST 7

Color additives exempt from certification (unless otherwise indicated) and permanently listed for use in **MEDICAL DEVICES**

**1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers** -  
Contact lenses - GMP - 73.3100

**1,4-Bis[4-(2-methacryloxyethyl)phenylamino]-9,10-anthraquinone copolymers** - Contact  
lenses GMP - 73.3106

**1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione** - Contact lenses - GMP - 73.3105

**Carbazole violet** - Contact lenses - GMP - 73.3107

**Chlorophyllin-copper complex** - Polymethyl-methacrylate bone cement -  $\leq 0.003\%$  by wt. -  
73.3110

**Chromium-cobalt-aluminum oxide** - Linear polyethylene surgical sutures -  $\leq 2\%$  by wt -  
73.1015, and contact lenses - GMP - 73.3110a

**Chromium oxide greens** - Contact lenses - GMP - 73.3111

**C.I. Vat Orange 1** - Contact lenses - GMP - 73.3112

**7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone** - Contact lenses - GMP - 73.3119

**2-[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5- benzenetriol** - For marking  
soft contact lenses with the letter R or L -  $< 0.11$  microgram in a contact lens - 73.3115

**16,23-Dihydrodinaphtho[2,3-a:2',3'-i]naphth[2',3':6,7]indolo[2,3-c]carbazole-  
5,10,15,17,22,24-hexone** - Contact lenses - GMP - 73.3117

**N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bis-benzamide** - Contact lenses - GMP  
- 73.3118

**16,17-Dimethoxydinaphtho[1,2,3-cd:3',2',1'-lm]perylene-5,10-dione** - Contact lenses - GMP - 73.3120

**4-[(2,4-Dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one** - Contact lenses - GMP - 73.3122

**D&C Blue #6** - Subject to certification. Surgical sutures. Limits are in regulation - 74.3106

**D&C Blue #9** - Subject to certification. Surgical sutures -  $\leq 2.5\%$  by wt - 74.1109

**D&C Green #5** - Subject to certification. Sutures -  $\leq 0.6\%$  by wt. of suture - 74.1205

**D&C Green #6** - Subject to certification. Surgical sutures, haptics and contact lenses. Limits are in regulation - 74.3206

**D&C Red #17** - Subject to certification. Contact lenses - GMP - 74.3230

**D&C Violet #2** - Subject to certification. Contact lenses - GMP..Absorbable sutures. Limits are in regulation. Polymethylmethacrylate intraocular lens haptics -  $\leq 0.2\%$  by wt. Absorbable meniscal tacks made from poly(L-lactic acid) -  $\leq 0.15\%$  by wt - 74.3602

**D&C Yellow #10** - Subject to certification. Contact lenses - GMP - 74.3710

**6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2-(3H)-ylidene)benzo[b]thiophen-3-(2H)-one** - Contact lenses - GMP - 73.3123

**FD&C Blue #2** - Subject to certification. Nylon surgical sutures -  $\leq 1\%$  by wt. of the suture - 74.3102

**FD&C Blue #2 Aluminum lake on alumina** - Subject to certification. Bone cement -  $\leq 0.1\%$  by wt. of the cement - 74.3102

**Iron oxides, synthetic** - Contact lenses - GMP - 73.3125

**Ferric ammonium citrate** - In combination with pyrogallol for coloring plain or chromic catgut sutures. Limit FAC-pyrogallol complex  $\leq 3\%$  by wt of the suture - 73.1025

**Logwood extract** - Surgical sutures -  $\leq 1\%$  by wt - 73.1410

**Mica-based pearlescent pigments** - Contact lenses - GMP - 73.3128

**[Phthalocyaninato(2-)] copper** - Subject to certification. Sutures -  $\leq 0.5\%$  by wt, Contact lenses - GMP - 74.3045

**Phthalocyanine green** - Contact lenses - GMP - 73.3124

**Poly(hydroxyethyl methacrylate)-dye copolymers** - Contact lenses - GMP - 73.3121. The color additives are formed by reacting one or more of the following dyes with poly(hydroxyethyl methacrylate):

- C.I. Reactive Black 5
- C.I. Reactive Blue 4
- C.I. Reactive Blue 19
- C.I. Reactive Blue 21

- C.I. Reactive Blue 163
- C.I. Reactive Orange 78
- C.I. Reactive Red 11
- C.I. Reactive Red 180
- C.I. Reactive Yellow 15
- C.I. Reactive Yellow 86

**Pyrogallol** - In combination with ferric ammonium citrate for coloring plain or chromic catgut sutures. Limit FAC-pyrogallol complex  $\leq$  3% by wt of the suture - 73.1025

**Titanium dioxide** - Contact lenses - GMP - 73.3126

**Vinyl alcohol/methyl methacrylate - dye reaction products** - contact lenses - GMP - 73.3127. The color additives are formed by reacting one or more of the following dyes with vinyl alcohol/methyl methacrylate copolymers:

- C.I. Reactive Black 5
- C.I. Reactive Blue 19
- C.I. Reactive Blue 21
- C.I. Reactive Orange 78
- C.I. Reactive Red 180
- C.I. Reactive Yellow 15

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